STATE OF KANSAS

Department of Health and Environment

Notice of Hearing on Proposed Amended Administrative Regulation

The Kansas Department of Health and Environment (KDHE), Division of Health, Bureau of Epidemiology, will conduct a public hearing on Friday March 31st, 2006, at 9:30 AM, in the Crumbine Conference Room, Fifth Floor, Curtis Building, 1000 SW Jackson St., Topeka, KS, to consider the adoption of a proposed amendment to existing disease regulations K.A.R. 28-1-2.

K.A.R. 28-1-2 includes the list of diseases reportable by physicians. Most reportable conditions are infectious. These lists need to be updated periodically, to reflect changes in diagnostic tests and in the list of national notifiable diseases maintained by the Centers for Disease Control and Prevention (CDC) and the Council of State and Territorial Epidemiologists (CSTE).

When a condition is added to the list, providers and facilities that submit reports for that condition are protected from liability incurred as a result of their reporting (K.S.A. 65-118).

Adding **"influenza deaths in children under 18 years of age"** was changed to monitor the incidence and track the basic characteristics of pediatric influenza deaths.

More information is needed to define the burden of influenza in children and develop appropriate strategies to prevent mortality associated with this vaccine preventable disease.

During the fall of 2003, there were several widely publicized reports of influenza-associated deaths in children. These accounts generated concern that children were disproportionately affected by influenza during the current season. In December 2003, CDC requested that states voluntarily report influenza-associated deaths in children <18 years of age during the 2003-04 season. During October 11, 2003 - March 22, 2004, CDC received a total of 142 reports of pediatric fatalities associated with laboratory-confirmed influenza. Whether this represents an increase over baseline is unclear, since comparative data do not exist.

There should be little or no economic impact in years with no reports in Kansas. If a report is received in Kansas there would be epidemiological follow-up for the case involving the local facility's time and effort and the KDHE epidemiologist or local health department time.

Adding **" any transmissible spongioform encephalopathy (TSE) or prion disease (indicate causative agent, if known)"**. Prion diseases are also referred to as transmissible spongiform encephalopathies (TSE). They occur in humans and animals, primarily affecting the central nervous system. Unlike other known infectious diseases, it

is believed to result from a change in the conformation or shape of a normal protein called cellular prion protein, which is present in large amounts in the brain as well as in other tissues. The abnormal prion can be and, under certain rare conditions that have not yet been fully determined, can transmit the disease. Currently, there are no cures for prion diseases. The average world-wide occurrence of one prion disease (Cruetzfeld Jacob's Disease, or CJD) is approximately one case per million people per year.

In 2003, the identification of two cases of Bovine Spongioform Encephalitis ("mad cow" disease) in North America, the report of a highly probable blood borne transmission of vCJD in the UK, and the increasing spread of chronic wasting disease of deer and elk (ale prion disease that has not yet shown to infect humans) indicate the need to continue enhancing human prion disease surveillance in this country. Such surveillance is needed to monitor the occurrence of any emerging forms of human prion disease (e.g., vCJD, or possible human chronic wasting disease) as well as other prion disease related public health issues.

Reporting of this disease would likely have little economic impact at the program level due to the extremely small numbers of cases that are expected, however, the reporting of a case could have a broader impact . That economic impact in such a case, expected to be extraordinarily rare, would be difficult to estimate but can be expected to be large in Kansas. Estimated costs to the program would primarily revolve around an epidemiologist's time for follow up.

Adding **"<u>arboviral disease, including West Nile virus, western equine encephalitis (WEE), and St. Louis encephalitis (SLE</u>)**' will change existing reporting to include the spectrum of disease rather than just the most severe manifestations of disease to determine the impact of the disease and interventions to prevent disease. Arbovirus encephalitis is reportable already. Many physicians and laboratories also report the full spectrum of West Nile Virus disease, following a request by KDHE in 2004. This change would effectively change what is presently occurring to regulation to increase accurate and complete reporting.

Other changes to 28-1-2: "**streptococcal invasive<u>, drug-resistant</u> disease from group A *Streptococcus* or *Streptococcus pneumoniae***" was changed to require only drug resistant strains be reported to follow what CDC and CSTE recommends. The public health response is focused on those cases where traditional treatment is not effective because of drug resistance. There is not a public health reason to track all cases of invasive streptococcal disease. It is expected that the change will decrease the number of cases to be reported and the follow up required to only those in which there might be a public health benefit.

Changed: **"*Escherichia coli* enteric infection from *E. coli* O157:H7 and other ~~enterohemorrhagic, enteropathogenic, and enteroinvasive~~ <u>shiga toxin-producing</u>**

***E. coli*, also known as STEC"** was changed to reflect more modernly used terminology to reduce confusion among reporting entities and improve reporting.

Economic Impact:

Cost to the agency

The number of disease reports submitted to the Bureau of Epidemiology and Disease Prevention in the Kansas Department of Health and Environment will increase, and will be incorporated into the existing staff workload. The Kansas Health and Environmental Laboratory will have to pay for the cost of additional tests on isolates sent by clinical laboratories. Most of the testing is anticipated to be requested by physicians in commercial laboratories, is already ordered, and will not be a result of these changes in the regulation. KDHEL does not test for transmissible spongioform encephalopathies (TSEs) or prion disease and does not propose to begin to do so, but testing through Case Western Reserve University would continue to be encouraged as is currently advised.

Local health departments will incur some modest additional costs when they receive a case report from a provider and they transmit it to KDHE. Most (80%) local health departments are linked to the KDHE HAWK system, an electronic disease reporting system that they can access to report these conditions to KDHE. It is estimated that each case report for both newly reported diseases will require about 5 minutes of a

clerical staff time, at an average cost of less than $2 per case. The anticipated number of new reports for Arboviral Disease addition is expected to be 200 cases and the TSE, or prion disease addition less than 10 total cases per year in Kansas.

Revising Streptococcal invasive disease follow-up to only those with potential public health implications would actually decrease state and local resources needed.

Therefore, the total direct cost of the additional reporting requirements should be less than $500.00 for all parties.

Cost to persons who will bear the costs and those who will be affected, (i.e., private citizens and consumers of the products or services) and are subject to the proposed rules and regulations or the enforcement:

As noted, the number of cases arising from these changes should be minimal and highly variable as to when they might occur. Not counting the human costs, the reporting related costs would be minimal and easily absorbed within already existing reporting requirements.

Costs to other governmental agencies or units:

As noted, the number of cases arising from these changes should be minimal. Some of the changes will offset existing confusion over reporting for certain diseases thereby offsetting any new costs in the aggregate.

The time period between the publication of this notice and the scheduled hearing constitutes a 60-day public comment period for the purpose of receiving written public comments on the proposed regulatory action. All interested parties may submit written comments prior to the hearing to Sharon Wenger, Bureau of Epidemiology, Curtis Building, 1000 SW Jackson St., Suite 210 Topeka, KS 66612. Comments may also be e-mailed to Sharon Wenger at swenger@kdhe.state.ks.us. All interested parties will be given a reasonable opportunity to present their views orally on the proposed regulatory action during the hearings. In order to give all parties an opportunity to present their views, it may be necessary to require each participant to limit any oral presentation to 5 minutes.

Copies of the proposed amendments and the economic impact statement may be obtained from the Kansas Department of Health and Environment, Bureau of Epidemiology (BEDP), by calling (785) 296-7032 and are also available at the BEDP website http://www.kdheks.gov/bedp/index.html. Questions pertaining to these proposed amendments should be directed to Sharon Wenger, (785) 296-7032.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the proposed amendments and the economic impact and environmental benefit statements in an accessible format. Requests for accommodation to participate in the hearing should be made at least five working days in advance of the hearing by contacting Sharon Wenger, (785) 296-7032.

Roderick L. Bremby

Secretary of Health and Environment

12-27-05

Kansas Department of Health and Environment
Proposed Amended Permanent Regulation

28-1-2. Designation of infectious or contagious diseases. (a) The following diseases shall be designated as infectious or contagious in their nature, and cases or suspect cases shall be reported within seven days, unless otherwise specified, in accordance with K.S.A. 65-118 and K.S.A. 65-128, and amendments thereto.

(1) Amebiasis;

(2) anthrax (report by telephone within four hours to the secretary);

(3) arboviral disease, including West Nile virus, western equine encephalitis (WEE), and St. Louis encephalitis (SLE);

(4) botulism (report by telephone within four hours to the secretary);

~~(4)~~ (5) brucellosis;

~~(5)~~ (6) campylobacter infections;

~~(6)~~ (7) chancroid;

~~(7)~~ (8) *Chlamydia trachomatis* genital infection;

~~(8)~~ (9) cholera (report by telephone within four hours to the secretary);

~~(9)~~ (10) cryptosporidiosis;

~~(10)~~ (11) cyclospora infection;

~~(11)~~ (12) diphtheria;

~~(12) encephalitis or meningitis, arboviral (indicate infectious agent whenever possible);~~

(13) ehrlichiosis;

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(14) *Escherichia coli* enteric infection from *E. coli* O157:H7 and other ~~enterohemorrhagic, enteropathogenic, and enteroinvasive~~ shiga toxin-producing *E. coli*, also known as STEC;

(15) giardiasis;

(16) gonorrhea;

(17) *Haemophilus influenzae*, invasive disease;

(18) hemolytic uremic syndrome, postdiarrheal;

(19) hepatitis B in pregnancy (report the pregnancy of each woman with hepatitis B);

(20) hepatitis, viral;

(21) hantavirus pulmonary syndrome;

(22) influenza deaths in children under 18 years of age;

(23) legionellosis;

~~(23)~~ (24) leprosy or Hansen's disease;

~~(24)~~ (25) listeriosis;

~~(25)~~ (26) Lyme disease;

~~(26)~~ (27) malaria;

~~(27)~~ (28) measles or rubeola (report by telephone within four hours to the secretary);

~~(28)~~ (29) meningitis, bacterial (indicate causative agent, if known, and report by telephone within four hours to the secretary);

~~(29)~~ (30) meningococcemia (report by telephone within four hours to the secretary);

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~~(30)~~ (31) mumps (report by telephone within four hours to the secretary);

~~(31)~~ (32) pertussis or whooping cough (report by telephone within four hours to the secretary);

~~(32)~~ (33) plague or *Yersinia pestis* (report by telephone within four hours to the secretary);

~~(33)~~ (34) poliomyelitis (report by telephone within four hours to the secretary);

~~(34)~~ (35) psittacosis;

~~(35)~~ (36) rabies, animal and human (report by telephone within four hours to the secretary);

~~(36)~~ (37) Rocky Mountain spotted fever;

~~(37)~~ (38) rubella, including congenital rubella syndrome (report by telephone within four hours to the secretary);

~~(38)~~ (39) salmonellosis, including typhoid fever;

~~(39)~~ (40) severe acute respiratory syndrome (SARS) (report by telephone within four hours to the secretary);

~~(40)~~ (41) shigellosis;

~~(41)~~ (42) streptococcal invasive, drug-resistant disease from group A *Streptococcus* or *Streptococcus pneumoniae*;

~~(42)~~ (43) syphilis, including congenital syphilis;

~~(43)~~ (44) tetanus;

~~(44)~~ (45) toxic-shock syndrome, streptococcal and staphylococcal;

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(46) any transmissible spongioform encephalopathy (TSE) or prion disease (indicate causative agent, if known);

~~(45)~~ (47) trichinosis;

~~(46)~~ (48) tuberculosis, active and latent (report active disease by telephone within four hours to the secretary);

~~(47)~~ (49) tularemia;

~~(48)~~ (50) varicella or chickenpox;

~~(49)~~ (51) yellow fever; and

~~(50)~~ (52) any exotic or newly recognized disease, and any disease unusual in incidence or behavior, known or suspected to be infectious or contagious and constituting a risk to the public health (report by telephone within four hours to the secretary).

(b) The occurrence of a single case of any unusual disease or manifestation of illness that the health care provider determines or suspects could be caused by or related to a bioterrorism act shall be reported within four hours by telephone to the secretary. The term "bioterrorism act," as used in this article, shall mean a dispersion of biological or chemical agents with the intention to harm. Each bioterrorism act shall be reported within four hours by telephone to the secretary. The following shall be considered bioterrorism agents when identified in the course of a possible bioterrorism act:

(1) Anthrax;

(2) plague;

(3) smallpox;

(4) tularemia;

(5) botulism;

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(6) viral hemorrhagic fever;

(7) Q fever or *Coxiella burnetii*;

(8) brucellosis; and

(9) any other infectious or toxic agent that can be intentionally dispersed in the environment.

(Authorized by K.S.A. 65-101 and 65-128; implementing K.S.A. 65-118 and 65-128 ~~and 65-202~~; effective May 1, 1982; amended May 1, 1986; amended Dec. 24, 1990; amended April 19, 1993; amended Jan. 12, 1996; amended Dec. 1, 1997; amended Feb. 18, 2000; amended, T-28-11-20-03, Nov. 20, 2003; amended March 5, 2004; amended P-_____.)

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